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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/824,587	04/03/2001	Lorraine D. Butlin	IMIN.P-032	8700
21121	7590	10/31/2003	EXAMINER	
OPPEDAHL AND LARSON LLP P O BOX 5068 DILLON, CO 80435-5068			NGUYEN, BAO THUY L	
			ART UNIT	PAPER NUMBER
			1641	
			DATE MAILED: 10/31/2003	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/824,587

Applicant(s)

BUTLIN ET AL.

Examiner

Bao-Thuy L. Nguyen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE _____ MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) _____ is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

1. As previously indicated, the numbering of claims is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not).

The claims were renumbered in paper number 10. Previously pending claims 19 and 20 are still pending and should be canceled.

Election/Restrictions

2. Claims 51-54 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 11.

This application contains claims drawn to an invention nonelected with traverse in Paper No. 11. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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4. Claims 48-50 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is unclear if the antibodies expressed by hybridoma cells lines ECACC 00032004 and ECACC 00032005 that have been deposited been made publicly available and all restrictions removed if allowed. It is also unclear if the hybridomas have been deposited under the Budapest Treaty and comply with 35 USC 112 (first paragraph) requirements for deposited biological materials. Clarification is required.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 21-23, 29, 35-38 and 44-47 are rejected under 35 U.S.C. 102(b) as being anticipated by Shah et al (US 4,900,662).

Shah discloses a method for measuring of an analyte pair consisting of the native protein and an initial, altered form of the native protein. Both measured values being useful for diagnosis. See column 1, lines 48-57. Specifically, Shah discloses a method for determining the initial elevated concentration level of CK-MM_A in patient serum following a myocardial infarction comprising determining the combined concentration of CK-MM_A and CK-MM_B. Shah discloses the use of anti-CK-MM antibody bound to a solid support and labeled antibodies for

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the capture and determination of the CK-MM_{A + B}. See column 4, line 35 through column 5, lines 20. Shah discloses simultaneous as well as step-wise process for the determination of CK-MM_A and CK-MM_B. Shah teaches that the combined levels of CK-MM_A and CK-MM_B provide a more accurate estimate of the time of infarction. See column 5, lines 45-49. The amount of the analyte pair and the ratio of native protein to the analyte pair are accurately determined the time of the initiation of the acute disease. Shah teaches the use of polyclonal and/or monoclonal antibodies and kits containing them for use in the method.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 24-28, 30-34 and 39-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shah et al in view of Creus et al., (Clinical Endocrinology. 1996 February. Vol. 44, No. 2, pp. 181-189).

See the discussion of Shah above. Shah differs from the instant invention in failing to teach the measurement of gonadotrophic hormones such as follicle-stimulating hormone (FSH).

Creus, however, discloses the characterization of an analyte belonging in the gonadotrophin family, specifically, serum FSH isoforms according to the carbohydrate structure inner to the sialic acid residues. Results from these studies are expressed in IU/I and as B/I ratios. See page 182, table 1 and page 187.

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Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the assay taught by Shah for the detection of hormones such as FSH taught by Creus and to express the results in terms of ratios because Creus shows that such method is well known and is conventional in the art. A skilled artisan would have been motivated to use the method taught by Shah to measure different isoforms of FSH because Shah discloses that diagnosis of acute disease is often based on abnormal levels of disease markers such as hormones in biological fluids, particularly when they change momentarily during the acute phase, and Creus teaches that a woman's endocrine status affects the circulating FSH isoforms, therefore, a complete evaluation of FSH using the immunoassays taught by Shah would have been desirable and convenient with the use of antibodies.

Double Patenting

9. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

10. Claims 21-50 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 18-22 and 26-28 of copending

Application No. 09/828,624. Although the conflicting claims are not identical, they are not

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patentably distinct from each other because they are both directed to a method for differentiating between two different isoforms (or states) of an analyte using immunoassays on contemporaneous samples and expressing the result as ratio of one over the other.

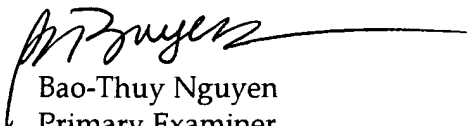
This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao-Thuy L. Nguyen whose telephone number is (703) 308-4243. The examiner can normally be reached on Tuesday and Thursday from 9:00 a.m. – 5:00 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (703) 305-3399. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 and (703) 305-3592.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.


Bao-Thuy Nguyen
Primary Examiner
23 July 2003